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U.S. Department of Commerce Patent and Trademark Office Attorney's Docket No. 06275-150003

Application No. 10/010,283

Information Disclosure Statement by Applicant (Use several sheets if necessary) Applicant

Carl-Axel Bauer et al.

Filing Date

Group Art Unit

R §1.98(b)

November 13, 2001

1617

			U.S. Pater	nt Documents			
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	Foreign Patent Documents or Published Foreign Patent Applications						
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(Other Documents (include Author, Title, Date, and Place of Publication)					
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- 2	CC	Compendium Suisse des Medicaments, 15th Ed. 1997/1998, Ed. Grand Public, compiled June 1996, pages 2-3, 419-420, 866 (in French)				
\sim	/ CD	Compendium Suisse des Medicaments, 18th Ed. 1997, compiled June 1996, pages 5, 849-851 and 1635-1636 (in French)				
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			U.S. Pater	nt Documents			
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	BA						

	Foreign Patent Documents or Published Foreign Patent Applications						
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation
7	BB	WO 97/11783	04/03/1997	WIPO			

	Other Documents (include Author, Title, Date, and Place of Publication)				
Examiner	Desig.				
Initial	ID	Document			
2	BC,	"American Thoracic Society: Standards for the Diagnosis and Care of Patients with Chronic Obstructive Pulmonary Disease," Am. J. Respir. Care Med. 152:S77-S121 (1995)			
1	BD,	"Atemstillstand" Pschyrembel Klinisches Wörtebuch (2002) (in German)			
	BE'	Auffarth et al., "Effects of inhaled budesonide on spirometric values, reversibility, airway responsiveness, and cough threshold in smokers with chronic obstructive lung disease" Thorax 46:372-377 (1991)			
	BF,	Barnes, "Inhaled steroids in COPD" The Lancet 351:766-767 (1998)			
	BĢ	Basic Reference Manual, vol. 1, revised ed. of 1988, issued by IMS International			
	ВН	"Bronchodilators and anti-inflammatories," Monthly Index of Medical Specialities (MIMS) 242-256 (09/1997)			
	BI	Boyd et al., "An Evaluation of Salmeterol in the Treatment of Chronic Obstructive Pulmonary Disease (COPD)," Eur. Resp. J. 10:815-821 (1997)			
	ВĴ	Burge et al. "Randomised, double blind, placebo controlled study of fluticasone propionate in patients with moderate to severe chronic obstructive pulmonary disease: the ISOLDE trial," British Med. J. 320:1297-1303 (2000)			
	BK	Davies et al., "Oral corticosteroid trials in the management of stable chronic obstructive pulmonary disease," Q. J. Med. 92:395-400 (1999)			
	. BL	"Disorders of the Airways," Current Medical Diagnosis and Treatment 1997 36th ed. pages 241-255, Stamford, CT: Appleton and Lange (1997)			
	ВМ	Dompeling et al., "Slowing the deterioration of Asthma and Chronic Obstructive Pulmonary Disease Observed during Bronchodilator Therapy by Adding Inhaled Corticosteroids," Ann. Intern. Med. 118(10):770-778 (1993)			
	BN	Engel et al., "A trial of inhaled budesonide on airway responsiveness in smokers with chronic bronchitis" Eur. Respir. J. 2:935-939 (1989)			
	ВО	Fabbri et al., "Global Strategy for the Diagnosis, Management and Prevention of COPD: 2003 update" Eur. Respir. J. 22:1-2 (2003)			
	BP	Flenley, "Chronic Obstructive Pulmonary Disease," Disease-A-Month 34:549-599 (1988)			
2	BQ	"Foradil" Compendium Suisse des Medicaments, Supplement 1a pages 7-8 (1991) (in French)			

Examiner Signature .	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if next communication to applicant.	not in conformance and not considered. Include copy of this form with

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Sul (Mc	bstitute Form PTO odified)	14440V 0 A 2014 SED	epartment of Commerce nt and Trademark Office	Attorney's Docket No. 06275-150003	Application No. 10/010,283	
	Information Disclosure Statement		itatement	Applicant Carl-Axel Bauer et al.		
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	Other D	ocuments (include Author, Title, Date, and Place of Publication)
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2	BR	"Foradil," Compendium Suisse des Medicaments, 15th Ed. 1997/1998, Ed. Grand Public, compiled June 1996, pages 419-420, 866 (in French)
	BS	"Foradil," Compendium Suisse des Medicaments, 18th Ed. 1997, compiled June 1996, pages 849-850 and 1635 (in French)
	BT	"Foradil" Patient information leaflet, published by IKS, Switzerland (12/1990) (in French)
	BU	Gibson et al., Respiratory Medicine Table of contents (2002)
	BV	"GOLD: Global Initiative for Chronic Obstructive Lung Disease," Executive Summary; National Institutes of Health, National Heart Lung and Blood Institute, NIH Publication No. 2701A, pages 1-30 (03/2001)
	BW	"GOLD: Global Initiative for Chronic Obstructive Lung Disease; Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease," based on April 1998 NHLBI/WHO Workshop, pages 1-100 (2004 Update)
	BX	Jeffery "Structural and inflammatory changes in COPD: a comparison with asthma" Thorax 53:129-136 (1998)
	BY	Keatings et al., "Effects of Inhaled and Oral Glucocorticoids on Inflammatory Indices in Asthma and COPD" Am. J. Respir. Crit. Care Med. 155:542-548 (1997)
	BZ	Kerstjens et al., "A Comparison of Bronchodilator Therapy with or without Inhaled Corticosteroid Therapy for Obstructive Airways Disease," New Eng. J. Med. 327:1413-1419 (1992)
	BAA	Leff et al., "Therapeutic Regimens in Chronic Obstructive Pulmonary Disease," Pulmon. Crit. Care Pharmacol. Therapeut. Ch. 86:837-844 (1996)
	BBB	Niewoehner et al., "Effect of Systemic Glucocorticoids on Exacerbations of Chronic Obstructive Pulmonary Disease" New Eng. J. Med. 340(25):1941-1947 (1999)
	ВСС	Norman, "COPD: New Developments and Therapeutic Opportunities" Drug News Perpect. 11(7):431-437 (1998)
	BDD	Pauwels et al., "Long-Term Treatment with Inhaled Budesonide in Persons with Mild Chronic Obstructive Pulmonary Disease Who Continue Smoking" N. Eng. J. Med. 340:1948-1953 (1999)
	BEE	Postma, "Inhaled therapy in COPD: what are the benefits?" Respiratory Medicine 85:447-449 (1991)
	BFF	"Pulmicort" ABPI Data Sheet Compendium, p. 146-147 (1995/1996)
	BGG	Schultze-Werninghaus, "Multicenter 1-Year Trial on Formoterol, a New Long-Acting β ₂ -Agonist, in Chronic Obstructive Airway Disease," Lung Suppl:83-89 (1990)
	внн	Siafakas et al., "Optimal Assessment and Management of Chronic Obstructive Pulmonary Disease (COPD)," Eur. Respir. J. 8:1398-1420 (1995)
	BII	Soriano et al., "Inhaled Corticosteroids with/Without Long-Acting b-Agonists Reduce the Risk of Rehospitalization and Death in COPD Patients," Am. J. Respir. Medic. 2:67-74 (2003)
	BJJ	Stalenheim et al., "Efficacy and Tolerance of a 12-Week Treatment with Inhaled Formoterol in Patients with Reversible Obstructive Lung Disease," Respiration 61:305-309 (1994)
	BKK	Stedman's Medical Dictionary, 25th ed., Baltimore: Williams and Wilkins; page 428
	BLL	Szafranski et al., "Efficacy and safety of budesonide/formoterol in the management of chronic obstructive pulmonary disease" Eur. Respir. J. 21:74-81 (2003)

Examiner Signature	Date Considered 11/30/06
EXAMINER: Initials citation considered. Draw line through citation if no next communication to applicant.	ot in conformance and not considered. Include copy of this form with

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	Other D	ocuments (include Author, Title, Date, and Place of Publication)
Examiner Initial	Desig. ID	Document
7	ВММ	Trechsel, "Foradil in medical practice; 7 case studies" Ciba Geigy (1992)
1	BNN	Van Schayck et al., "Do patients with COPD benefit from treatment with inhaled corticosteroids?" Eur. Respir. J. 9:1969-1972 (1996)
	воо	Vestbo et al., "Long-term effect of inhaled budesonide in mild and moderate chronic obstructive pulmonary disease: a randomised controlled trial," Lancet 353:1819-1823 (1999)
	ВРР	Watson et al., "Failure of Inhaled Corticosteroids to Modify Bronchoconstrictor or Bronchodilator Responsiveness in Middle-Aged Smokers with Mild Airflow Obstruction" Chest 101(2):350-355 (1992)
2	BQQ	Weiner et al., "Inhaled Budesonide Therapy for Patients with Stable COPD," Chest 108:1568-1571 (1995)

Examiner Signature	Date Considered 11/30/06
EXAMINER: Initials citation considered. Draw line through citation if next communication to applicant.	not in conformance and not considered. Include copy of this form with

[Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. ,06275-150003	Application No. 09/670,457
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	(37 CFR §1.98(b))			

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	muai		5,795,564	8/18/1998	Aberg et al.			43,011.2
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$\bar{}$	Foreign Patent Documents or Published Foreign Patent Applications Translation								
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8		AE	0 416 951 A1	03/13/1991	Europe	<u> </u>		L	<u>. </u>

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	Dealg.	Document
	MAF	CA 126:259329 Renkema et al.
	AG	CA 126:259329 Kenkema et al. C. Wyser et al., "Neue Aspekte in der Behandlung des Asthma bronchiale und chronisch C. Wyser et al., "Neue Aspekte in der Behandlung des Asthma bronchiale und chronisch obstruktiver Lungenkrankheiten", 1997, Schweiz Med Wochenschr, Volume 127 page 885-page 890 obstruktiver Lungenkrankheiten", 1997, Schweiz Med Wochenschr, Volume 127 page 385-page 890
4	AH	Jean H. Marsac, Fotis D. Vlastos, and Jacques G. Lattouque September 1989, Vol. 63, number 3, inhaled steroids in the treatment of asthma" Annals of Allergy September 1989, Vol. 63, number 3,
	Al	pages 220-224 Francis P.V. Maesen, M.D., Ph.D., FC.C.P. Joseph J. Smeets, Hendrik L. L. Gubbelmans, M.D., and Petra G. M. A. Zweers, M.D. "Formoterol in the Treatment of Nocturnal Asthma" Chest 98 4
	AJ .	October 1990 pages 886-870 Francis P.V. Maesen, M.D., Ph.D., F.C.C.P., Joseph J. Smeats; Hendrik L. L. Gubbelmans, M.D., Francis P.V. Maesen, M.D., Ph.D., F.C.C.P., Joseph J. Smeats; Hendrik L. L. Gubbelmans, M.D., and Petra G.M. A. Zweers, M.D., "Bronchodilator Effect of Inhaled Formoterol vs. Salbutamol Over and Petra G.M. A. Zweers, M.D., "Bronchodilator Effect of Inhaled Formoterol vs. Salbutamol Over 12 Hours" Chest/97/3/March 1990
	AK	12 Hours" Chest/97/3/March 1990 Romain A. Pauwels, M.D., Claes-Goran Lofdahl, M.D., Peter J. Barnes, M.D., and Anders Ullman, M.D., "Effect of Inhaled Formoterol and Budesonide on Exacerbations of Asthma" Vol. 337 Number 20, November 13, 1997
	AL	Curriculum Vitae of Charles Richard William Beasley
-	AM	Stannory Declaration of Charles Richard William Beasley
	AN	D
	AO	Additive effects of Budesonide and Formoterol in Reducing Severe Asimira Exactly Sweden Months, O'Byrne et al. On behalf of international study group and Astra Draco AB Land Sweden Months, O'Byrne et al. On behalf of international study group and Astra Draco AB Land Sweden
	AP	Massachuseus Medical Society, November 13, 1757, 188
	AQ	Response by Astra to EPO, dated November 22, 1995

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Dupticate		AQ	Huib A.M. Kerstjens, MD., et al. "A Comparison of Brochomiator Interapy with Corticosteroid Therapy for Obstructive Airways Disease" November 12, 1992, The New England Journal of Medicine, Vol. 327 number 20, pages 1413-1419.
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